K091362

5. 510(K) SUMMARY

JUN 29 2009

Applicant Name and Address:

EZ-Pedo Inc.
2350 Professional Drive Suite 200
Roseville, CA 95661

Establishment Registration Number: None at this time
Device Name: Ceramic Pediatric Preformed Crown
Classification: 872.3330
Classification Name: Preformed Crown
Product Code: ELZ

Date Prepared: May 8, 2009

510(k) Contact Person and Phone Number:

Company: Dr. Jeffery P. Fisher
Chief Executive Officer, EZ-Pedo Inc.
(916) 768 -7592 (Phone)
(916) 774-9437 (Fax)

Name and Address of Manufacturing Site

Company: EZ-Pedo Inc., .
2350 Professional Drive Suite 200
Roseville, CA 95661

Manufacturing Site Contact Person and Phone Number:

Elizabeth Weaver
(916) 768 -7592

Predicate Devices:

The EPI Ceramic Pediatric Preformed Crown is claimed to be substantially equivalent to the following legally marketed predicate devices:

1. King Dental Corporation Artificial Teeth (Class I, K931162)
2. NuSmile Preformed Crowns – Primary Crowns (Class I, 510(k) exempt)
3. Procera Bridge Zirconia (K041283)
4. C5 Medical Werks ZirDent CAD/CAM Blocks (K081253)

General Description:

The EPI Ceramic Pediatric Preformed Crown is a temporary tooth restoration. The dental crown is a tooth-shaped "cap" that is placed over a tooth – covering the tooth to restore its shape and size, strength, and/or to improve its appearance. The preformed crowns are manufactured in specific sizes for a proper fit, which are contained within the range of sizes commonly available for existing preformed crowns. Sizing is exclusively determined by the dentist for their particular patient and the EPI crowns are not meant to undergo further manipulation by the dentist. The EPI Ceramic Pediatric Preformed Crown is secured within the patient's mouth using standard dental adhesion techniques. The crowns, when cemented into place, fully encase the entire visible portion of a tooth that lies at and above the gum line.

The EPI Ceramic Pediatric Preformed Crown is made of Zirconia. Zirconia is a biologically inert, high-tech ceramic material (dental porcelain) intended for use in the construction of zirconium oxide ceramic prosthetics. Because the EPI crowns are distributed in their final, finished form, there are no pellets, casting alloys, powders or auto mix systems that require further manipulation by the dentist.

Indications for Use:

The EZ-Pedo Inc. Ceramic Pediatric Preformed Crown is intended to be used as a functional restoration, including for a badly decayed deciduous (baby) tooth, until the adult tooth erupts. The EZ-Pedo Inc. Ceramic Pediatric Preformed Crown is indicated for use in infants, children and adolescents.

Summary of Technical Characteristics

The technical characteristics of the EPI Ceramic Pediatric Preformed Crown are substantially equivalent to those of the King Dental Corporation Artificial Teeth (K931162) and the NuSmile Preformed Primary Crowns. Both devices are preformed crowns, and the sizes of the EPI crowns are contained within the sizes available for existing preformed crowns (i.e. NuSmile Preformed Crown – Primary Crowns, Class I devices, 510(k) exempt).

The technical characteristics of the EPI Ceramic Pediatric Preformed Crown are also substantially equivalent to those of the Nobel Biocare Procera Bridge Zirconia device (K041283) and the C5 Medical Werks CAD/CAM Blocks (K081253). All three devices are dental products intended for long term placement in the mouth, specifically contacting the gums (mucous membrane). All three devices are made of biologically inert Zirconia material. In addition, both the EPI crown and the Nobel Biocare Procera Bridge are precision milled from a single densely sintered Zirconia block. The EPI crown is precision milled directly from the C5 CAD/CAM blocks.

Summary of Non-Clinical Testing

Non-clinical product testing was conducted on the preformed crown, including material characterization and biocompatibility. Results of the testing demonstrated that the EPI crown is adequate for its intended use.

Conclusion

The EPI Ceramic Pediatric Preformed Crown is substantially equivalent with respect to the indications for use, technological characteristics, sizing, performance characteristics and processing to the following the legally marketed predicate devices:

I. King Dental Corporation Artificial Teeth (K931162)
II. NuSmile Preformed Crowns – Primary Crowns (Class I, 510(k) exempt)
III. Nobel Biocare Procera Bridge Zirconia (K041283)
IV. C5 Medical Werks CAD/CAM Blocks (K081253)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2009

Dr. Jeffery Fisher
CEO
EZ-Pedo, Incorporated
2350 Professional Drive, Suite 200
Roseville, California 95661

Re: K091362
Trade/Device Name: Ceramic Pediatric Preformed Crown
Regulation Number: 21 CFR 872.3330
Regulation Name: Preformed Crown
Regulatory Class: 1
Product Code: ELZ
Dated: May 8, 2009
Received: May 8, 2009

Dear Dr. Fisher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

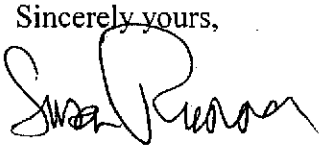
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: EZ-Pedo Inc. Ceramic Pediatric Preformed Crown

Indications for Use:

The EZ-Pedo Inc. Ceramic Pediatric Preformed Crown is intended to be used as a functional restoration for primary teeth, including for a badly decayed deciduous (baby) tooth, until the adult tooth erupts. It is not intended for permanent restoration. The EZ-Pedo Inc. Ceramic Pediatric Preformed Crown is indicated for use in infants, children, and adolescents.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert Betz DDS for Dr. Kevin Mulry
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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